DETAILED ACTION

Response to Amendment

1. The amendment filed April 16, 2010 has been entered.

2. Claims 1, 2, 21 and 26 have been amended and claims 12-20 and 33-36 have been cancelled.

3. Claims 1-7, 9-11 and 21-32 are currently pending and have been fully considered.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1, 2, 7, 21, 22, 25, 26 and 30-32 are rejected under 35 U.S.C. 102(b) as being anticipated by GUO et al (US 6,033,866).

Regarding claim 1, GUO et al teaches a biosensor with a reagent layer comprising an enzyme and redox compound or internal reference (c. 2, l. 31-34) and a sensing electrode with a mediator (c. 2, l. 23-26). The mediator and internal reference are taught in column 2, lines 33-53 to be any number of combinations which inherently will nearly all have different redox potentials. Furthermore, these two mediators and the enzyme are taught to be "sandwiched" together or in face-to-face contact (c. 2, l. 10-16), which inherently allows for mixing.

Regarding claim 2, in column 2, line 52 of GUO et al, ferrocyanide is identified as a possible internal reference species, known in the art to be a reduced form of a reversible redox couple. In combination with the ferrocyanide, numerous mediators can be utilized which have a lower redox potential, including that of nickelocene identified as a mediator component in column 2, line 38.

Regarding claim 7, GUO et al teaches the use of a working electrode and reference electrode in column 4, lines 24-26. The reference electrode is structurally the same a counter electrode. Therefore the functionality of the electrode does not change its inherent ability to be a counter electrode for the purpose of this action. MPEP section 2114 teaches the method of use of an apparatus cannot separate it from a structurally equivalent piece of prior art.

Regarding claim 21, GUO et al teaches a biosensor with a reagent layer comprising an enzyme and redox compound or oxidizable species (c. 2, l. 31-34) and a sensing electrode with a mediator (c. 2, l. 23-26). The mediator and oxidizable species are taught in column 2, lines 33-53 to be any number of combinations. Furthermore, these two mediators (the oxidizable species and mediator) and the enzyme are taught to be "sandwiched" together or in face-to-face contact (c. 2, l. 10-16) with each other and in turn both electrodes, which inherently allows for mixing. Please note the claim does not require the prior

mixing of the enzyme, mediator and oxidizable species together prior to the application, but simply the mixing of the enzyme, mediator and oxidizable species themselves. The addition of the pieces separately further supports this contention. The term batch is interpreted to mean that the pieces are brought together on the sensor wherein the batch is the necessary pieces of one sensor for example. Moreover, since each tangible piece is present discretely they are inherently added separately or in batch.

Regarding claims 22 and 30-32, in column 2, line 52 of GUO et al, ferrocyanide is identified as a possible internal reference species, known in the art to be a reduced form of a reversible redox couple. In combination with the ferrocyanide, numerous mediators can be utilized which have a lower redox potential, including that of nickelocene identified as a mediator component in column 2, line 38. Moreover, ferricyanide is also identified in the above citations as being a possible mediator. This combination with the ferrocyanide would render equal redox potentials.

Regarding claims 25 and 26, these claims are directed to the method of operating the sensor while they depend of claim 21 which is directed to the method of making the sensor. Since the same materials (the numerous oxidizable species and mediators of use in GUO et al) and method of making are present as the internal reference and mediator as required by claim 21, the

biosensor would function just as required when electronics outside the sensor supply the two potentials to the sensor itself.

6. Claims 21-22 and 30-32 are rejected under 35 U.S.C. 102(b) as being anticipated by HODGES et al (US PG PUB 2001/0052470).

Regarding claims 21, 30, 31 and 32, HODGES et al teaches a biosensor with reagent mixture comprising an enzyme (GOD), ferricyanide (mediator) and ferrocyanide (internal reference) in paragraph 9. The specification of the instant application discloses the internal reference can be a mediator species on page 3, line 24 of the instant application and this combination is taught on pages 15 and 16 of the specification as working in accordance with the present invention. Therefore, ferrocyanide can be interpreted to function as the internal reference. The chemical application or batch formation is discussed in paragraphs 69-70.

Regarding claim 22, the example of ferrocyanide as the internal reference and ferricyanide as the mediator is described on pages 15 and 16 of the specification to redox at the desired potentials.

Claim Rejections - 35 USC § 103

7. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

8. Claims 3-6, 23 and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over GUO et al (US 6,033,866), in view of BLOCZYNSKI et al (US 5,520,786).

GUO et al teaches all the limitations of claim 1, including the use of numerous mediators as the mediator of the instant application in column 2, lines 33-41.

Regarding claim 3, BLOCZYNSKI et al teaches the use of mediator 3-phenylimino-3H-phenothiazine in the abstract.

At the time of the invention, it would have been obvious to one of ordinary skill in the art to substitute the known mediator (3-phenylimino-3H-phenothiazine, BLOCZYNSKI et al) for another known mediator (i.e. nickelocene or any of the other oxidized listed components of GUO et al) because they would both yield the predictable result of functioning as an electron transfer agent in the reaction. (GUO et al, c. 2, l. 5-9)

Regarding claim 4, GUO et al teaches the ferrocyanide to be present as the internal reference.

Regarding claims 5 and 6, since the same materials are present as the internal reference and mediator, the biosensor would function just as required when electronics outside the sensor supply the two potentials to the sensor itself. For the purpose of this apparatus claim, the biosensor would be capable of reacting with the potentials as sufficiently required by the claim, as these are inherent

reactions which the biosensor will perform when the process conditions specified are applied.

Regarding claim 23, BLOCZYNSKI et al teaches the use of mediator 3-phenylimino-3H-phenothiazine in the abstract.

At the time of the invention, it would have been obvious to one of ordinary skill in the art to substitute the known mediator (3-phenylimino-3H-phenothiazine, BLOCZYNSKI et al) for another known mediator (i.e. nickelocene or any of the other oxidized listed components of GUO et al) because they would both yield the predictable result of functioning as an electron transfer agent in the reaction. (GUO et al, c. 2, l. 5-9)

Regarding claim 24, GUO et al teaches the ferrocyanide to be present as the internal reference.

9. Claims 9-11, 27 and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over GUO et al (US 6,033,866), in view of NAGAKAWA et al (US PG PUB 2004/0245121 A1).

GUO et al teaches all the limitations of claim 1, including the use of numerous mediators as the mediator of the instant application in column 2, lines 33-41.

Regarding claims 9 and 27, NAGAKAWA et al teaches the use of a Ru complex mediator with substitutions, or ruthenium hexamine, as discussed in column 3, line 57- column 4, line 9.

At the time of the invention, it would have been obvious to one of ordinary skill in the art to substitute the known mediator (ruthenium hexamine, NAGAKAWA et al) for another known mediator (i.e. nickelocene or any of the other oxidized listed components of GUO et al) because they would both yield the predictable result of functioning as an electron transfer agent in the reaction. (GUO et al, c. 2, l. 5-9)

Regarding claim 10 and 28, GUO et al teaches the ferrocyanide to be present as the internal reference.

Regarding claim 11, NAGAKAWA et al teaches the use of the mediator with glucose oxidase for glucose measurements in column 4, lines 19-29 as does GUO et al in column 2, l. 32-33.

10. Claims 23-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over HODGES (US PG PUB 2001/0052470), in view of BLOCZYNSKI et al (US 5,520,786).

HODGES et al teaches all the limitations of claim 21.

Regarding claim 23, BLOCZYNSKI et al teaches the use of mediator 3-phenylimino-3H-phenothiazine in the abstract.

At the time of the invention, it would have been obvious to one of ordinary skill in the art to substitute the known mediator (3-phenylimino-3H-phenothiazine, BLOCZYNSKI et al) for another known mediator (ferricyanide, HODGES et al) because they would both yield the predictable result of functioning as an electron transfer agent in the reaction. (Summary of invention and column 1, lines 47-50, BLOCZYNSKI et al)

Regarding claim 24, HODGES et al teaches the ferrocyanide to be present as the internal reference, as discussed in the above rejection.

Regarding claims 25 and 26, these claims are directed to the method of operating the sensor while they depend of claim 21 which is directed to the method of making the sensor. Since the same materials and method of making are present as the internal reference and mediator as required by claim 21, the biosensor would function just as required when electronics outside the sensor supply the two potentials to the sensor itself.

11. Claims 27-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over HODGES et al (US PG PUB 2001/0052470), in view of NAGAKAWA et al (US PG PUB 2004/0245121 A1).

HODGES et al teaches all the limitations of claim 21.

Regarding claim 27, NAGAKAWA et al teaches the use of a Ru complex mediator with substitutions, or ruthenium hexamine, as discussed in column 3, line 57- column 4, line 9.

At the time of the invention, it would have been obvious to one of ordinary skill in the art to substitute the known mediator (ruthenium hexamine, NAGAKAWA et al) for another known mediator (ferricyanide, HODGES et al) because they would both yield the predictable result of functioning as an electron transfer agent in the reaction. (NAKAGAWA et al, c. 1, l. 37-46)

Regarding claim 28, HODGES et al teaches the ferrocyanide to be present as the internal reference, as discussed the above rejection.

Regarding claim 29, HODGES et al teaches the enzyme to be GOD or glucose oxidase in paragraph 9. Furthermore, NAGAKAWA et al teaches the use of the mediator with glucose oxidase for glucose measurements in column 4, lines 19-29 but will also be effective with any oxidation-reduction enzyme, as in HODGES et al.

Response to Arguments

12. Applicant's arguments filed April 15, 2010 regarding independent claim 21 and the rejection of HODGES et al have been fully considered but they are not persuasive.

13. Applicant argues on page 8 that since HODGES et al utilizes an oxidized species which reacts to be present, it isn't added separately.

a. The fact that the ferrocyanide is not present upon the addition of the enzyme and ferricyanide teaches that it is added separately. Furthermore, in the arguments submitted, applicant argues that the ferrocyanide at the end of the reaction is indicative of the glucose concentration. This argument is irrelevant. The ferrocyanide which functions as the oxidizable species is that which is added to the reagent after the addition of the ferrocyanide and its functionality at the end of the reaction is not impactful to the claim.

14. Applicant's arguments with respect to claim 1 and its dependents have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

15. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

b. KUHN et al US 5,385,846 teaches the use of both ferrocyanide and ferricyanide in the same reagent layer.

c. TANIIKE et al US PG PUB 20010006149 teaches the use of multiple mediators at once in the same reagent.

16. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

17. Any inquiry concerning this communication or earlier communications from the examiner should be directed to KOURTNEY R. SALZMAN whose telephone number is (571)270-5117. The examiner can normally be reached on Monday to Thursday 6:30AM-5PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nam Nguyen can be reached on (571) 272-1342. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Nam X Nguyen/
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krs
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